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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,223	07/14/2000	Jay A. Nadel	UCSF-085CIP	7019

7590

04/08/2003

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.

09/616,223

Applicant(s)

Nadel et al

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 2, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) 4-9, 11, and 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10, 12-19, and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10, 13 6) ☐ Other:

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DETAILED ACTION

This Office action is in response to the communication filed May 2, 2002, Paper No. 11.

Claims 1-26 are pending in the instant application.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 24 (the second claim 24 listed in the original claims) has been renumbered claim 25.

Response to Arguments and Amendments

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 1-3, 10, 12-19 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention, for the reasons of record set forth in the Office action mailed January 2, 2002, Paper No. 9..

Applicant's arguments filed May 2, 2002 have been fully considered but they are not persuasive. Applicants argue that adequate written description has been provided in the instant disclosure for the broad genus comprising any and/or all EGF-R antagonists that bind to EGF-R because some tyrosine kinase inhibitors, antibodies that bind a factor that stimulates EGF or EGF-R production, and TGF-alpha binding antibodies have been disclosed in the specification. Applicants assert furthermore that working examples of the tyrosine kinase inhibitors BIBX1522 and AG1478 have been provided in the specification which also contribute toward providing adequate written description for this broad genus. Contrary to Applicants' assertions, the wide array of species encompassed within the claimed genus, comprising any and/or all antagonists that bind to EGF-R, have not been adequately described in the instant disclosure. A cursory examination of EGF-R related publications within the scientific literature indicates the existence of a very wide array of compounds and reagents comprising antagonists that bind to EGF-R (see new rejections below). No distinguishing features concisely shared by members of this broad genus have been provided in the instant disclosure. The scope of the claims includes numerous structural variants, including organic molecules, antibodies and other peptides, and the genus is highly variant because a significant number of structural differences between members of the genus is permitted. Concise structural features that could distinguish structures or compounds within the genus from others is missing from the disclosure. Applicants' argument that the

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written description requirement only requires description of identifying characteristics is not persuasive because the complete structure of a representative number of species in addition to the species' identifying characteristics are needed. Applicants have not provided sufficient description to meet these requirement. The instant disclosure fails to provide a representative number of species to describe this broad genus claimed. Therefore, the rejection for lacking adequate written description is maintained.

Claims 1-3, 10, 12-19 and 26 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed, for the reasons of record set forth in the Office action mailed January 2, 2002, Paper No. 9.

Applicant's arguments filed May 2, 2002 have been fully considered but they are not persuasive. Applicants argue that sufficient working examples have been provided for the scope of the claims, drawn to methods of reducing goblet cell hyperplasia in an airway of an individual comprising the administration of any and/or all antagonists of epidermal growth factor receptor (EGF-R) that binds to the EGF-R. The examples provided in the instant specification, including examples 1, 2 and 3, teach the reduction in airway mucus hypersecretion in animal models comprising the intratracheal instillation or the intraperitoneal administration of the tyrosine kinase inhibitor BIBX1522. The specification also teaches the reduction of mucus (MUC5) expression in target cells in vitro following the administration of BIBX1522 or tyrphostin AG129. No examples have been provided, however, for the reduction of goblet cell hyperplasia or the

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treatment of nasal polyps in any and/or all individual organisms comprising the administration, by any route, of any and/or all EGF-R antagonists that bind EGF-R. A representative number of the various members of this very broad genus, comprising any and/or all EGF-R antagonists that bind to EGF-R, has not been shown to be effectively delivered to the appropriate target cells in the airways of any organism whereby airway goblet cell hyperplasia has been reduced or nasal polyps have been treated. The examples provided of the in vitro administration of BIBX1522 or of AG129, or of the intratracheal instillation or intraperitoneal (pre)administration of BIBX1522, or the antagonism of EGF-R by anti-TGF-alpha antibody are not representative of the successful delivery to the appropriate target cells in the airway of individuals - **by any and/or all routes of administration** - any and/or all antagonists of EGF-R which bind to EGF-R in an organism, whereby airway goblet cell hyperplasia has been reduced, or whereby nasal polyps have been treated..

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 10, 12-16 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, lines 3-4 and in claim 26, line 2, it is unclear what is meant by the term “antagonist that binds the EGF-R to a patient”. Appropriate clarification is requested.

In claim 26, line 2, it is unclear what is meant by the term “suffering nasal polyps”.
Inserting “from” before nasal will be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Khetarpal et al.

Khetarpal et al teach pharmaceutical formulations comprising EGF-R antagonists that are selective for EGF-R and inhibit transphosphorylation of EGF-R (See entire document, especially pages 216-21).

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoneda et al.

Yoneda et al teach pharmaceutical formulations comprising EGF-R antagonists that are selective for EGF-R, bind to EGF-R and inhibit its transphosphorylation (See entire document, especially pages 4430-4432).

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Masui et al.

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Masui et al teach pharmaceutical formulations comprising EGF-R antagonists that are selective for EGF-R, bind to EGF-R, and inhibit its transphosphorylation (See entire document, especially pages 1002-1005).

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchdunger et al.

Buchdunger et al teach pharmaceutical formulations comprising EGF-R antagonists that are selective for EGF-R, bind to EGF-R, and inhibit its transphosphorylation (See entire document, especially pages 2334-2335 and 2337).

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

April 6, 2003


RAM R. SHUKLA, PH.D
PATENT EXAMINER